BIOLASE | BIOLASE Technology, Inc.

K122368

510(k) Summary

Orthopedic iPlus Soft Tissue Laser

April 26, 2013

MAY - 2 2013

Company:	Biolase Technology, Inc. 4 Cromwell Irvine, CA 92618
Establishment Registration:	2027755
Company Contact:	Colleen Boswell Vice President, Regulatory Affairs Telephone: 949-226-8470 Fax: 949-273-6688
Trade Name:	Orthopedic iPlus Soft Tissue Laser
Common Name:	Er, Cr: YSGG laser
Classification Name:	Powered laser surgical instrument
Classification:	Class II
Regulation Number:	Laser surgical instrument for use in general and plastic surgery and in dermatology, per 21 CFR 878.4810
Panel:	General and Plastic Surgery
Product Code:	GEX
Predicate Devices:	Sciton's *Profile Multi-Platform System* (K060033) CoolTouch Inc.'s *CoolTouch Varia Nd:YAG Surgical Laser* (K092964) Richard Wolf Medical Instruments Corporation's *MegaPulse Laser System* (K090776) Fotona's *Fotona Dualis Laser System* (K021548)

Device Description:

The *Orthopedic iPlus Soft Tissue Laser* is an erbium, chromium, yttrium, scandium, gallium garnet (Er, Cr:YSGG) solid state laser that provides optical energy to the user controlled distribution of atomized water droplets at 2.78 μm (2780 nm). The laser consists of a cabinet which houses the power supply, the cooling system, microcontroller, laser, foot switch, and fiber optic for delivery of laser energy with fiber optic handpiece setup. The *Orthopedic iPlus Soft Tissue Laser* utilizes direct laser energy either with or

without water for cooling and hydration to perform soft tissue incision, excision, resection, ablation, vaporization, coagulation and hemostasis.

Indications for Use:

The *Orthopedic iPlus Soft Tissue Laser* is intended for use as a laser surgical instrument in orthopedic and podiatric surgery. It is indicated for the following Indications for Use, including the previously cleared dental indications, for completeness:

DENTAL INDICATIONS FOR USE

General Indications*

- Class I, II, III, IV and V cavity preparation
- Caries removal
- Hard tissue surface roughening or etching
- Enameloplasty, excavation of pits and fissures for placement of sealants

*For use on adult and pediatric patients

Root Canal Hard Tissue Indications

- Tooth preparation to obtain access to root canal
- Root canal preparation including enlargement
- Root canal debridement and cleaning

Root Canal Disinfection

- Laser root canal disinfection after endodontic treatment

Endodontic Surgery (Root Amputation) Indications

- Flap preparation - incision of soft tissue to prepare a flap and expose the bone
- Cutting bone to prepare a window access to the apex (apices) of the root(s)
- Apicoectomy - amputation of the root end
- Root end preparation for retrofill amalgam or composite
- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex

***NOTE:** Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.*

Bone Surgical Indications

- Cutting, shaving, contouring and resection of oral osseous tissues (bone)
- Osteotomy

Soft Tissue Indications including Pulpal Tissues*

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Flap preparation - incision of soft tissue to prepare a flap and expose the bone
- Flap preparation - incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
- Frenectomy and frenotomy
- Gingival troughing for crown impressions

- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscesses
- Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulp extirpation
- Pulpotomy as an adjunct to root canal therapy
- Root canal debridement and cleaning
- Reduction of gingival hypertrophy
- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex

NOTE: *Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.*

- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

*For use on adult and pediatric patient

Laser Periodontal Procedures

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacterial perpetration of the pocket lining junctional epithelium
- Removal of granulation tissue from bony defects
- Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours)
- Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)
- Osseous crown lengthening
- Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage
- Waterlase MD Er,Cr:YSSG assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)

ORTHOPEDIC INDICATIONS FOR USE

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis, with or without an arthroscope, in contact and non-contact with tissue, in orthopedic and podiatric surgery, including:

- Soft and cartilaginous tissue in small and large joints (e.g., knee meniscectomy, debridement of inflamed synovial tissue)

Substantial Equivalence:

The subject device proposed indications for orthopedic and podiatric surgery are substantially equivalent to the indications of Sciton's *Profile Multi-Platform System* (K060033), CoolTouch Inc.'s *CoolTouch Varia Nd:YAG Surgical Laser* (K092964), Richard Wolf Medical Instruments Corporation's *MegaPulse Laser System* (K090776) and Fotona's *Fotona Dualis Laser System* (K021548). Additionally, the *Orthopedic iPlus Soft Tissue Laser* is substantially equivalent in materials, dimensions, weight, operating voltage, current frequency, laser medium, wavelength, max power, power mode, pulse energy, pulse duration, cooling and aiming beam to specifications of Sciton's *Profile Multi- Platform System* (K060033), CoolTouch Inc.'s *CoolTouch Varia Nd:YAG Surgical Laser* (K092964), Richard Wolf Medical Instruments Corporation's *MegaPulse Laser System* (K090776) and Fotona's *Fotona Dualis Laser System* (K021548).

Conclusion:

Comparison of this device with the previously cleared devices provided in this 510(k) submission demonstrates the safety and effectiveness of this device for the above indications, and supports substantial equivalence to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Biolase Technology, Inc.
% Ms. Colleen Boswell
Vice President, Regulatory Affairs
4 Cromwell
Irvine, California 92618

May 2, 2013

Re: K122368
Trade/Device Name: Orthopedic iPlus Soft Tissue Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and Plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 18, 2013
Received: March 19, 2013

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122368

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.05.01 14:13:48 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ____K122368_____

Bone Surgical Indications

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -A
2013.05.01 14:14:14 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ____K122368_____

- Soft tissue crown lengthening
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510(k) Number ____K122368_____